



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,705	04/17/2001	Yuki Abe	01149/HG	7090
1933 7590 01/13/2005 FRISHAUF, HOLTZ, GOODMAN & CHICK, PC 767 THIRD AVENUE 25TH FLOOR NEW YORK, NY 10017-2023			EXAMINER KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/836,705	Applicant(s) ABE ET AL.	
	Examiner Kathleen M Kerr	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-43,45,56,57,60-65,67 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-43,45,60-64,67 and 68 is/are rejected.
- 7) ☒ Claim(s) 56,57 and 65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on July 15, 2004), Applicants filed a response and amendment received on September 17, 2004. Said amendment amended Claim 40, 42, 43, 56, and 64 and cancelled Claims 58-59 and 66. Thus, Claims 1-57, 60-65, and 67-68 are pending in the instant Office action.

Election

2. Claims 1-57, 60-65, and 67-68 are pending in the instant application. Claims 1-39, 44, and 46-55 are withdrawn from consideration as non-elected inventions; said inventions are not subject to rejoinder since method claims are being examined herein. Claims 40-43, 45, 56-57, 60-65, and 67-68 will be examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the foreign application 2000-116591 filed in Japan on April 18, 2000 and 2000-117458 filed in Japan on April 19, 2000 as requested in the declaration. Receipt was previously acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. Said papers are not in English; no English translations have been filed.

Information Disclosure Statement

4. The information disclosure statement originally filed on September 17, 2004 has been considered. The documents have now been considered as evidenced by the Examiner's initials on the attached copy.

Withdrawn - Claim Objections

5. Previous objection to Claim 43 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicant's amendment rewriting the claim in independent form.
6. Previous objection to Claim 65 for depending from a rejected claim is withdrawn.

New Claim Objections

7. Claims 40 and 43 are objected to for misspelling "Pennicilium" in its 4th occurrence. Other occurrences are spelled properly. Correction is required.
8. Claim 42 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 42 seeks limit differently limit what which is excluded from the scope of Claim 40. By narrowing was can be excluded (going from anything encoding SEQ ID NO:44 to only excluding SEQ ID NO:43), the scope of Claim 40 is broadened (now being able to include things that encode SEQ ID NO:44 but that which aren't exactly SEQ ID NO:43).
9. Claims 56, 57, and 65 are objected to for containing redundant language that is arduous to read. The Examiner suggests the following rewrite of Claim 56:

Art Unit: 1652

---56. A method for producing ML-236B comprising:

- (a) culturing a *Penicillium* host cell having been transformed by pSAKexpR and
- (b) recovering ML-236B from the resultant culture;

wherein said *Penicillium* host cell is selected from the group consisting of *Penicillium citrinum*, *Penicillium brevicompactum*, and *Penicillium cyclopium*.---

Withdrawn - Claim Rejections - 35 U.S.C. § 112

10. Previous rejection of Claim 59 under 35 U.S.C. § 112, second paragraph, is withdrawn by virtue of Applicant's cancellation of said claim.

11. Previous rejection of Claims 40-43, 45, 59-64, and 66-68 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicant's amendment removing the exclusion of mlcE from the claims.

New - Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 40-43, 45, 60-64, and 67-68 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "corresponding to" is unclear. Must the nucleotide sequence actually encode SEQ ID NO:44, for example, or is some degree of homology allowed? Clarification is required.

The Examiner also notes that the claims are arduous to read. The Examiner suggests the following for clearer claim language:

Art Unit: 1652

---40. A method for producing ML-236B comprising:

- (a) culturing a *Penicillium* host cell having been transformed by a vector comprising a nucleotide sequence encoding mlcR, wherein said vector does not comprise a nucleotide sequence encoding at least one of mlcA, mlcB, mlcC, and mlcD and
- (b) recovering ML-236B from the resultant culture;

wherein said *Penicillium* host cell is selected from the group consisting of *Penicillium citrinum*, *Penicillium brevicompactum*, and *Penicillium cyclopium*;

and wherein mlcR has the amino acid sequence of SEQ ID NO:42, mlcA has the amino acid sequence of SEQ ID NO:44, mlcB has the amino acid sequence of SEQ ID NO:46, mlcC has the amino acid sequence of SEQ ID NO:48, and mlcD has the amino acid sequence of SEQ ID NO:50.

---42. A method for producing ML-236B comprising:

- (a) culturing a *Penicillium* host cell having been transformed by a vector comprising a nucleotide sequence encoding mlcR, wherein said vector does not comprise a nucleotide sequence encoding at least one of mlcA, mlcB, mlcC, and mlcD and
- (b) recovering ML-236B from the resultant culture;

wherein said *Penicillium* host cell is selected from the group consisting of *Penicillium citrinum*, *Penicillium brevicompactum*, and *Penicillium cyclopium*;

wherein mlcR has the amino acid sequence of SEQ ID NO:42;

and wherein said vector does not comprise at least one nucleotide sequence selected from the group consisting of SEQ ID NO:43, SEQ ID NO:45, SEQ ID NO:47, and SEQ ID NO:49.---

---43. A method for producing ML-236B comprising:

- (a) culturing a *Penicillium* host cell having been transformed by a vector comprising a nucleotide sequence encoding mlcR, and
- (b) recovering ML-236B from the resultant culture;

wherein said *Penicillium* host cell is selected from the group consisting of *Penicillium citrinum*, *Penicillium brevicompactum*, and *Penicillium cyclopium*;

and wherein mlcR has the amino acid sequence of SEQ ID NO:42,

and wherein said producing occurs in the absence of a recombinant polynucleotide sequence encoding at least one of mlcA, mlcB, mlcC, and mlcD and wherein mlcA has the amino acid sequence of SEQ ID NO:44, mlcB has the amino acid sequence of SEQ ID NO:46, mlcC has the amino acid sequence of SEQ ID NO:48, and mlcD has the amino acid sequence of SEQ ID NO:50.---

13. Claims 43 and 64 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “gene” is used in a manner that is inconsistent with the art. While the specification does disclose both the genomic and cDNA of mlcA-D and mlcR,

Art Unit: 1652

a gene also includes all regulatory sequences, which are not disclosed and do not correspond to SEQ ID NOs:43 or 44, for example. Clarification of the use of the term “gene” is required.

The Examiner notes that Claim 43 is distinguished from Claim 40 in that no recombinant SEQ ID NO:43 (anything encoding SEQ ID NO:44) is allowed in the claimed method, whereas in Claim 40, recombinant SEQ ID NO:43 can be present, just not on the same vector.

Withdrawn - Claim Rejections - 35 U.S.C. § 103

14. Previous rejection of Claims 40, 42, 43, 45, 60, 61, 63, 64, and 66-68 under 35 U.S.C. § 103(a) as being obvious over Abe *et al.* (WO 01/12814) in view of Yu *et al.* (Appl. Envir. Microbiol. (1995) 61(6): 2365-2371) and further in view of Chang *et al.* (Appl. Envir. Microbiol. (1995) 61(6): 2372-2377) is withdrawn by virtue of the Examiner’s reconsideration. In the absence of a positive function for mlcR in the prior art, one would have no reason to express this member of the gene cluster other than “to try” and see what happens. This is insufficient motivation for the combination of references.

The Examiner acknowledges receipt of the declaration under 37 C.F.R. § 1.132.

Summary of Pending Issues

15. The following is a summary of the issues pending in the instant application:
- a) Claims 40 and 43 stand objected to for misspelling “Pennicilium” in its 4th occurrence.
 - b) Claim 42 stands objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.
 - c) Claims 56, 57, and 65 stand objected to for containing redundant language.
 - d) Claims 40-43, 45, 60-64, and 67-68 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “corresponding to”.
 - e) Claims 43 and 64 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “gene”.

Conclusion

16. Claim 56-57 and 65 are objected to; Claims 40-43, 45, 60-64, and 67-68 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **NON-FINAL** based on the new grounds of rejection set forth herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

January 7, 2005